TAVR: Who Should Prep the Device?
The Role of Industry Representatives' Participation in the Cath Lab

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Dr. David Rizik of Scottsdale, Arizona, asks: After years of having the industry clinical support staff prep the transcatheter aortic valve replacement (TAVR) valves in the lab (without a single adverse event because of faulty prep, to my knowledge) some administrators have now begun to raise questions as to why industry representatives are doing the prep. My questions:

1. Are most institutions comfortable with Edwards and Medtronic clinical support staff prepping the valves?
2. Have some institutions "mandated" that cath lab nurses or techs prep the valve?
3. Do you personally, as TAVR operator, participate in prepping the valves?

Amir Kaki, Detroit, Michigan: Our staff prep the valves. The rep is there during the prep for every case. It works well. We find the reps add value in our cases and are welcome.

I don't doubt that industry representatives bring value. What I do wonder about, though, is how risk-averse our world is, and what role this plays in how directly involved they are or should be in individual procedures.

— Bonnie Weiner, MD

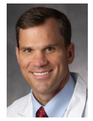
Ramon Quesada, Miami, Florida: At our Institution, the techs prep the valves, clips, etc. The industry clinical specialists are present, but do not scrub. We have not had any adverse events. Early in our experience, we did participate in the preparation of the valves, but we don't anymore.

Steve Ramee, New Orleans, Louisiana: (1) We still have the industry clinical rep present for all cases, and they do the valve prep. (2) I do trust them. (3) I never prep the valve myself. I don't disagree with doing it without industry support, but I enjoy having another pair of eyes and another brain in the room.

Mauricio Cohen, Miami, Florida: Reps come in the room and assist with valve preparation. It maintains consistency and we have longstanding relationships with the reps. They teach our techs and there is a good symbiotic relationship. On the other hand, there is significant staff turnover in the cath lab, which may compromise safety. Our institution has not mandated that our techs/nurses prep the valve. I am happy with our current arrangement.

Another question is about the case plans. I have never felt entirely comfortable with reps providing us the CT analyses. I end up relying on them because our institution will not buy 3mensio (Pie Medical Imaging) so we can perform the CT analysis independently.

Bonnie Weiner, Worchester, Massachusetts: As a disclaimer, I don't do TAVR. I think this is a response to potential liability issues, as the reps have no standing from the standpoint of credentials at the institution. We have seen this with pacemaker reps and similar individuals (maybe some surgical reps) who have changed programming, assisted in procedures, and documented in medical records. The latter having been a bigger issue in the pre-EMR days, but there are still some paper records even in digital environments. I don't doubt that industry representatives bring value. What I do wonder about, though, is how risk-averse our world is, and what role this plays in how directly involved they are or should be in individual procedures.



William Fearon, Palo Alto, California: At Stanford, typically the rep preps the valve, although the staff are trained, and at times do it with the rep, or alone when a rep is unavailable. At our VA, it is mandated that the staff prep the valves, although the rep is present and participates in the case. I do not participate in prepping the valve, except to oversee it and to confirm correct orientation and alignment.

David Cohen, Roslyn, New York: Over the past 12 years, I have done structural work in 2 different labs with slightly different approaches to device prep:

MAHI (Mid America Heart Institute), Kansas City, Missouri:

1. TAVR: Rep preps device with assistance from technical staff. MD input limited to checking device orientation and inflation volume.
2. MitraClip (Abbott Vascular): Physicians prep device with close supervision by device rep (not scrubbed).

St. Francis Hospital, Roslyn, New York:

1. TAVR: Rep preps device. MD input limited to checking device orientation and inflation volume.
2. MitraClip: Staff preps device with close supervision by device rep (not scrubbed).

I am very comfortable with having the reps prep the devices and can't say that I have observed a faulty prep in all my time doing these procedures (rare issue with CoreValve [Medtronic] tab positioning, but always identified on fluoroscopy prior to device insertion). Quite frankly, given issues with staff turnover that are common these days, I am quite comfortable having the most experienced person in the room (i.e., the device rep) prep the devices. From a patient perspective, I think this is the safest way to proceed. In fact, I would submit that any insistence of the hospital on having our staff prep the devices is clearly motivated by legal/insurance concerns and not by patient safety.

Aaron Kaplan, Hanover, New Hampshire: In a follow-up to Dave's last comment, that "...having our staff prep the devices is clearly motivated by legal/insurance concerns and not by patient safety", I would talk directly with the institution's legal counsel, and 1) frame the issue as Dave has done and 2) show that peer

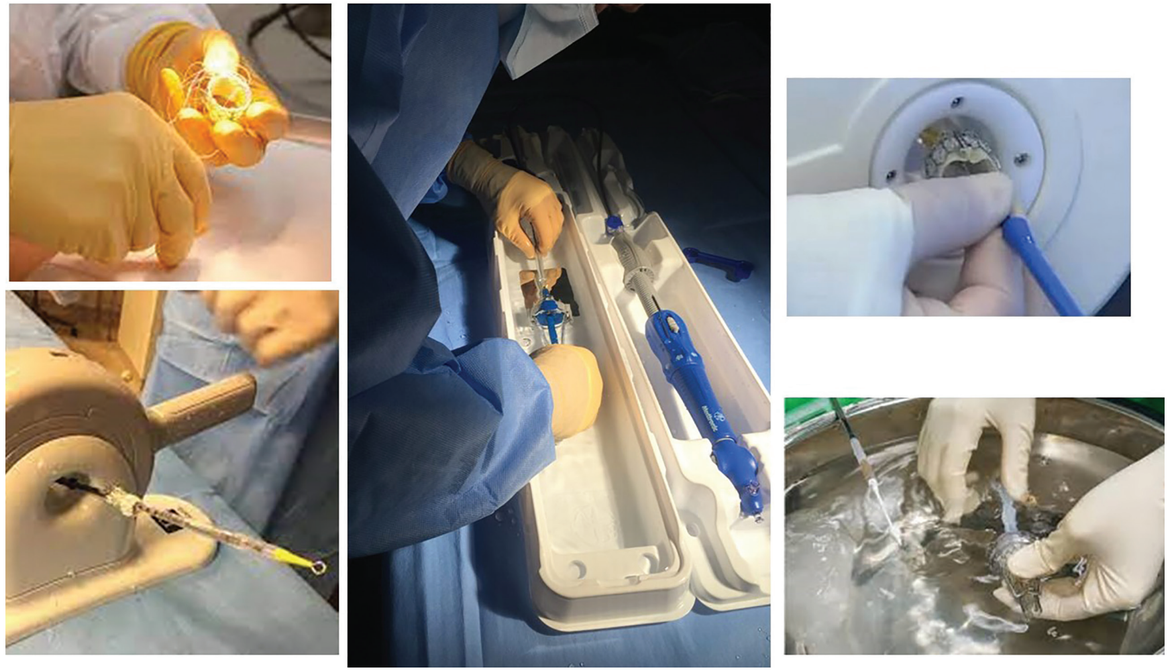


Figure 1. Transcatheter aortic valve replacement (TAVR) prep.

institutions routinely have industry reps participating. It is counsel's job to help work with you on this issue so that you can continue provide a high standard of care.

Mike Ragosta, Charlottesville, Virginia: At the University of Virginia, the techs prep the device with industry often present and providing helpful tips to the techs, but not required for us to function. With staff turnover, seems like we are constantly training techs to prep devices, so industry has been key to keeping our staff trained. The physicians do not prep the devices. The devices can be complicated to prepare correctly and are obviously very expensive; not so simple as prepping a stent. Overall, we find the industry folks to be knowledgeable about troubleshooting the device, highly professional, and a valuable resource and member of the team.

Regarding some of the legal concerns that have been voiced, I would think that not having industry present would be more of a legal concern if something went wrong with the device.

Bob Applegate, Winston-Salem, North Carolina: I think David's points are spot on. Our registered cardiovascular invasive specialist (RCIS) staff prep the TAVR devices, are trained by the reps, and supervised by them. I would feel totally comfortable to have the reps prep the devices and echo his concern that staff turnover has substantially thinned the staff experience level.

Mort Kern, Long Beach, California: Years ago, we stopped having industry reps participate in the hands-on cath lab procedures that we wanted the nurses/techs to learn, and reduce liability and risk from error if associated with someone not on staff at the hospital. You may recall the neurosurgical story about the implant of an antibiotic spinal cord pump where the reps in the lab set up the sterile implant and loaded the wrong dose of antibiotics, and handed it to the scrub nurse who handed it to the surgeon, ultimately causing patient harm. Who is liable? Of course, the hospital and doctor.

After that, we continued to have reps in the lab to assist indirectly, but never scrubbed, only to direct how the nurse sets up the Doppler, Rotablator (Boston Scientific), AngioJet (Boston Scientific), etc. No sterile gloves were to be given to non-employees so that there would be no blame for error outside our own control.

Every lab has reps come and demonstrate new devices, teach setups, watch, and comment during the procedures. But in our lab, the "no gloves" rule for the reps remains in place. It is a necessity for interventional cardiology and perhaps other procedural specialties to have a well of expertise in the reps who renew our knowledge base and assist us in setting up complex devices. The administration could help by understanding the business over which they are ultimately responsible and for which they are fearful of lawsuits, while not interfering in the safe practice of medicine.

Sam Butman, Cottonwood, Arizona: First, I confess that I am not involved in TAVR procedures. Nonetheless, I am older than many of you and have American history available to me. There will come a time somewhere in this country when a malpractice suit regarding a misplaced, damaged, or even an infected valve changes how we do things. Juries, the common man/woman, and hospital administrators all assume that only medical caregivers are involved in the care of patients, not industry reps in the hospital environment.

An industry rep in the room who is significantly involved, as was the case years ago for orthopedic or early angioplasty cases, and is physically involved (or perhaps not involved), could elicit serious frowns from a malpractice jury and it will cost money. A jury of our "peers" is bewildered by the fact that the "doctor" or his/her "team" did not personally prep the device to be inserted into a patient. It's just a fact of life in this unique country of ours.

Up until recently, only cath lab staff could prep valves. These "valve loaders" became prized employment prospects for some of the companies, and many went on to bigger and better jobs. When we had a good pipeline, it was great to see people go on to careers that they wanted to pursue (some came back). However, as volumes increased, attrition of workers during/after pandemic, desire to stagger cases in rooms, more days doing valve, this became harder to maintain.

— Duane Pinto, MD

My recommendation is to start prepping the devices for the inevitable time when your hospital will tell you to do so, if not simply to be able to say you can and do. Reps should only watch and teach. Heaven forbid, when directly asked, the operator does not do so. Remember, cardiac cath lab staff, administration, and others will be part of a suit and all you need is one to suggest that the operator does not know how, does not commonly prep it, or did not in the case at hand. And yes, of course, I have often had reps in the room, but a long time ago made sure that stayed at an arm's length from the table and the equipment.

I think the Society for Cardiovascular Angiography and Interventions (SCAI) (all of us), led by some of the people who have opined here, might benefit by having a proactive meeting of industry, physicians, hospital admin, and medico-legal eagles sit down and create a guiding document regarding this issue to serve as everything everyone has suggested, and believes is best for all of us and our patients. This would serve as a framework for how to do it right going forward and make it a win-win. Opportunity knocks!

Bonnie Weiner, Worchester, Massachusetts: I agree that this is a balancing act, with the patient being the focus (always). As I stated before, I fully understand and support the value of the reps. That said, I suspect that in most facilities where reps are more actively involved, administration/legal is unaware of the extent of their involvement. If they were, I believe there would be more pushback and restriction.

Duane Pinto, Boston, Massachusetts: We have gone the other direction. Up until recently, only cath lab staff could prep valves. These "valve loaders" became prized employment prospects for some of the companies, and many went on to bigger and better jobs. When we had a good pipeline, it was great to see people go on to careers that they wanted to pursue (some came back). However, as volumes increased, attrition of workers during/after pandemic, desire to stagger cases in rooms, more days doing valve, this became harder to maintain. We took a poll from Edwards and Medtronic, and we were apparently the only lab in the northeast that was 100% not industry. We formulated a formalized plan/policy, with the hospital requiring documentation of training, etc., and tracking of metrics such as misloads, etc. We also ensure no patient contact and that the valve is passed off to an MD and inspected/accepted by an MD (already done for Evolut [Medtronic] anyway). This poses an interesting question of whether the most experienced person should prep a valve under duress (pop-out, etc.). Bringing up this idea led to a discussion at the hospital level to create policies that encompassed all therapeutic areas where different things are done in ortho, neuro, interventional radiology, GI, etc., to codify the role of expert industry representatives who are "training/supporting/prepping" unfamiliar and familiar equipment.

Susheel Kodali, New York City, New York: I agree with the comments made by most. The reps scrub and prep the TAVRs in our lab, and assist with prepping the MitraClip by guiding the techs. The challenge, as highlighted by many, is the turnover in the cath lab staff. We do not have a consistent team in the room. Training the techs would require a significant investment. In addition to the turnover, there is also the issue of volume. In some labs (perhaps not the ones on this email chain), there are 25 TAVRs done a year (~2 a month). If you don't have the same tech in every case, it would be a very inexperienced person prepping the device. I would argue prepping the device is a critical part of the procedure. Besides assuring it is prepped currently (right orientation, no bubbles, etc.), there is also the concern of leaflet damage during the prep process, which may have longer-term consequences. I would propose that if the rep is not prepping the device, it should be the physician, as they are the one likely to have the most experience, given the turnover and the different staff in each case. I personally favor the reps prepping over the physicians.

Jeff Marshall, Atlanta, Georgia: I like David Cohen's idea, as most TAVR programs that I am familiar with do have company reps, unscrubbed, in the cath lab/hybrid room.

Amir Kaki, Detroit, Michigan: Very interesting takes. We do about 100 valves a year and the docs have never prepped the valve for TAVR. For MitraClips, maybe 25 a year, our staff prepares the clip with a non-gloved rep supervising and guiding them, because Abbott policies don't allow them to touch the device, so they tell us. In Detroit, we barely have enough staff to keep cath labs open at some of our hospitals. The safest approach for patients is having the experience and expertise of the most knowledgeable person guiding, doing, or supervising this critical part of the procedure. In our case, this person happens to be the rep. We have had not a single issue and do not intend to change our current approach.

The Bottom Line

Mort Kern, Long Beach, California: The use of industry representatives with their procedural expertise is of great help to the new and complex structural procedures, as well as other sophisticated devices used for coronary interventions. The transfer of expertise to the full-time cath lab staff is a continuous process and should be encouraged, but should not completely replace lab staff responsibilities for this critical step. This experience transfer is particularly critical, since recent experience of staff turnover can leave a knowledge gap for TAVR and other structural procedures. The issue of liability must be considered for supervision of all medical procedures in our labs and the ultimate responsibility remains with the hospital and physicians who set local policy. ■

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